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10/687,479	10/16/2003	Bruce L. Riser	FP0806.1 CON	7965

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,479	RISER ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,8,32 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 7-8, 32, 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 11/19/2007 is acknowledged.

2. Claims 1-2, 7-8, 32 and 35 are pending and currently under examination as they read on a method for diagnosing a renal disorder.

3. The following rejections are necessitated by the amendment filed on 11/19/2007.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 7-8, 32 and 35 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements for the same reasons as set forth in the Office Action mailed on 05/15/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "Claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Claims 1, 7, and 32, as amended above, recite a contacting step. As amended claims 1, 7, and 32 recite a contacting step, as requested by the Examiner, the rejection of these claims, and of dependent claims 2, 8,

and 35, is overcome, and Applicants respectfully request withdrawal of the rejection of these claims under 35 U.S.C. 112, 2nd paragraph."

It is the Examiner's position that the amendments to the claims do not overcome the instant rejection. In particular, the claims now recite a contact step, but the contact step does not correlate with the detection of CTGF because there is no step of detecting the antibody bound to the CTGF in the sample. In the instant claims, the CTGF may be detected independently of the contact step with antibody to CTGF.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 7-8, 32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for: a method for diagnosing **a renal disorder** in a subject having increased levels of glucose, the method comprising: (a) obtaining a urine sample from the subject; (b) contacting the urine sample with an antibody specific to CTGF; (c) detecting the level of CTGF protein in the urine sample; and (c) comparing the level of CTGF protein in the urine sample to a standard level of CTGF protein, wherein an increased level of

CTGF protein is indicative of the presence of the **renal disorder** of claim 1; wherein the increased levels of glucose are associated with diabetes of claim 2; A method for diagnosing **a renal disorder** in a subject having hyperglycemia, the method comprising: (a) obtaining **a** urine sample from the subject; (b) contacting the urine sample with an antibody specific to CTGF; detecting the level of CTGF protein in the urine sample; and (c) comparing the level of CTGF protein in the urine sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the presence of the **renal disorder** of claim 7; wherein the hyperglycemia is associated with diabetes of claim 8; A method for diagnosing **a renal disorder** in a subject having diabetes, the method comprising: (a) obtaining a urine sample from the subject; (b) contacting the urine sample with an antibody specific to CTGF; (c) detecting the level of CTGF protein in the urine sample; and (c) comparing the level of CTGF protein in the urine sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the presence of **the renal disorder** of claim 32; and wherein **the renal disorder** is diabetic nephropathy of claim 35 for the same reasons as set forth in the Office Action mailed on 05/15/2007.

Pages 46-57 of the specification disclose in vitro mouse data showing a correlation between the presence of CTGF in various kidney samples and cells with renal disease. Page 57 discloses the detection of CTGF in urine from 8 "patients being treated with a variety of kidney diseases" and from 3 normal healthy controls. The instant application discloses that 3 of the 8 patients were diabetic. All 8 patient samples (100%) and 1 normal healthy control sample (33%) had detectable CTGF. A small CTGF fragment was present in 3 out of 3 diabetic patients according to the instant specification.

The specification does not disclose a method of detecting CTGF in a urine sample that diagnoses diabetic neuropathy, or a renal disorder in a subject having increased levels of glucose, associated with diabetes, in a subject having hyperglycemia, or in a subject having diabetes. At the very best, Example 12 discloses a method of detecting a renal disorder in a subject having diabetes by detecting CTGF in urine. However, 1 out of the 3 control patients also had CTGF in their urine, which shows that the ability to diagnose any renal disease on the basis of the level of CTGF is very unpredictable. Nguyen et al. teaches that although the mean urinary CTGF level of patients with diabetic neuropathy was 1.6 fold higher than in control subjects that there was extensive overlap between patient and control groups. So, although it is statistically significant, the difference is less impressive in this large-scale study than was previously reported (PTO-892, Reference U, page 86, middle column, second full paragraph). It is suggested that the level of CTGF among patient samples correlates with severity of renal disease, rather than presence since control levels overlapped with patient samples (In particular, page 87, last paragraph). The reference goes on to teach that clinical studies will be necessary to evaluate urinary CTGF as an additional parameter for monitoring renal function in diabetic neuropathy (In particular, page 87, last paragraph). Therefore, the art shows that using CTGF to diagnose any single renal disease is unpredictable, much less all of the recited renal diseases and pathologies.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Applicants respectfully disagree. Regarding the Examiner's statement that "using CTGF to diagnose any renal disorder is unpredictable," Applicants note that, first, the claims as currently amended do not recite "any ... renal disorder," but are limited to recitation of renal disorders associated with diabetes, hyperglycemia, and increased levels of glucose. Second, Nguyen et al. states that, despite overlap between patient and control groups in the Nguyen studies, "[a] significant difference in U-CTGF was observed ... between patients with diabetic nephropathy and healthy control subjects," and concludes that "U-CTGF is significantly increased in diabetic nephropathy." (Nguyen et al., pages 84-85 and page 86, respectively.) Therefore, Nguyen, published after the filing date of the above-referenced application, validates the invention as described in the present claims, that an increased level of CTGF protein in a
urine sample is indicative of the presence of a renal disorder associated with, e.g., diabetes. For at least these reasons, Applicants submit that pending claims 1, 2, 7, 8, 32, and 35 are fully enabled, and withdrawal of this basis for the rejection is respectfully requested.

In summary, claims are 1, 2, 7, 8, 32, and 35 are fully enabled for at least the reasons provided above. Claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Accordingly, withdrawal of the rejection of these claims under 35 U.S.C. 112, 1st paragraph, as failing to comply with the enablement requirement, is thus respectfully requested.

Also, the Examiner noted that U.S. Provisional Patent Application Nos. 60/099,471 and 60/112,855 disclose that 4 of the 8 patients were diabetic, but the instant application states that 3 of the 8 patients were diabetic. The Examiner requested clarification. The correct number is 3. The specifications of U.S. Provisional Patent Application Nos. 60/099,471 and 60/112, 855 erroneously stated "4," but this was corrected to read "3" in the instant specification as filed. That the correct number is 3 is evidenced, for example, by the immunoblot blot presented in Figure 18 in the present application, corresponding to Figure 13 in U.S. Provisional Patent Application No.60/112,855, which contains 3 lanes labeled D, each corresponding to samples obtained from a diabetic patient. "

It is the Examiner's position that Nguyen et al. shows in Table 1 on page 85 that the CTGF level ranges in control and diabetic nephropathy patients significantly overlap. Control patients have 78-114 pmol/24 hours and diabetic neuropathy patients have 96-258 pmol/24 hours. Therefore, "levels" of 96-114 pmol/24 hours would not diagnose diabetic nephropathy, much less any renal disease. Further, the higher "average" level of CTGF in diabetic

nephropathy patients is not persuasive, given that the ranges overlap to such a degree. One patient sample is not an average and one patient sample having 96-114 pmol/24 hours could not be used to diagnose diabetic nephropathy, much less any recited renal disorder. Given this information, Nguyen does not support the claimed invention, as alleged by Applicant. It remains the Examiner's position that a skilled artisan would be required to perform undue experimentation to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-2, 7-8, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,232,064 (PTO-892, Reference A) in view of U.S. Patent 5,753,517 (PTO-892, Reference B) as evidenced by the specification on page 2 paragraphs [0007] and [0008]; and page 4, paragraph [0012].

The '064 patent teaches: a method for diagnosing a renal disorder (kidney fibrosis) in a subject having increased levels of glucose, the method comprising: (a) obtaining a sample from the subject; (b) contacting the sample with an antibody specific to CTGF; (c) detecting the level of CTGF protein in the sample; and (c) comparing the level of CTGF protein in the sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the

presence of the renal disorder (kidney fibrosis) of claim 1; wherein the increased levels of glucose are associated with diabetes (kidney fibrosis) of claim 2; A method for diagnosing a renal disorder in a subject having hyperglycemia (kidney fibrosis), the method comprising: (a) obtaining a sample from the subject; (b) contacting the sample with an antibody specific to CTGF; detecting the level of CTGF protein in the sample; and (c) comparing the level of CTGF protein in the sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the presence of the renal disorder (kidney fibrosis) of claim 7; wherein the hyperglycemia is associated with diabetes (kidney fibrosis) of claim 8; A method for diagnosing a renal disorder in a subject having diabetes (kidney fibrosis), the method comprising: (a) obtaining a sample from the subject; (b) contacting the sample with an antibody specific to CTGF; (c) detecting the level of CTGF protein in the sample; and (c) comparing the level of CTGF protein in the sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the presence of the renal disorder of claim 32; and wherein the renal disorder is diabetic nephropathy (kidney fibrosis) of claim 35.

The claimed invention differs from the prior art by the recitation of wherein the sample is urine.

The '517 patent teaches using urine to detect the level of urinary albumin to assess renal function and degree of kidney damage (In particular, column 1, lines 16-19, column 3, lines 6-11, column 9, lines 47-55 and claims 1 and 9).

It would have been obvious to use the urine sample of the '517' patent in the method of diagnosing a renal disorder associated with kidney fibrosis of the '064 patent because the '064 patent teaches using a sample suspected of containing CTGF. The '517 patent teaches that urine

is a sample containing a marker (albumin) that is associated with kidney damage and renal dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art to use a sample that comes directly from kidneys which has been known in the past to contain markers for kidney damage and renal dysfunction in the method for diagnosing a renal disorder by measuring the level of CTGF in that sample.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "Applicants submit that the '064 patent relates generally to diagnosing pathological states in a subject suspected of having pathology characterized by a cell proliferative disorder. The '064 patent does not disclose methods as recited in instant claims 1, 7, and 32, directed to methods for diagnosing a renal disorder in *"a* subject having increased levels of glucose," *"in* a subject having hyperglycemia," or *"in a* subject having diabetes," respectively. Additionally, the '064 patent does not disclose methods for diagnosing a renal disorder in the above-identified subjects by detecting the level of CTGF protein in a urine sample, as recited in claims 1, 7, and 32.
>
> Therefore, the '064 patent fails to disclose the methods recited in claims 1, 7, and 32, and their dependent claims 2, 8 and 35. Thus, the '064 patent fails to anticipate claims 1, 2, 7, 8, 32, and 35, and Applicants respectfully request withdrawal of the rejection of these claims under this section."

It is the Examiner's position that the '064 patent does teach diagnosing a renal disorder in a subject "having increased levels of glucose" in claim 1, "having hyperglycemia" in claim 7, "having diabetes" in claim 32 and "diabetic neuropathy" in claim 35 because the specification on page 2 paragraphs [0007] and [0008]; and page 4, paragraph [0012] teaches that diabetic neuropathy and renal disorders associated with increased glucose or hyperglycemia all have kidney fibrosis as a common pathway to progression. The genus of those individual with kidney fibrosis includes patients with increased glucose, hyperglycemia and diabetic neuropathy. The same method is being performed in the same patient population, so the recited renal disorders are inherently diagnosed and the claims are anticipated.

10. Claims 1-2, 7-8, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Ito et al. (IDS filed on 12/15/2003) in view of Gygi et al. (PTO-892, Reference V) and U.S. Patent 5,753,517 (PTO-892, Reference B).

Ito et al. teaches a method for diagnosing a renal disorder (diabetic nephropathy) in a subject having increased levels of glucose, the method comprising: (a) obtaining a sample from the subject; (c) detecting the level of CTGF protein (mRNA) in the sample; and (c) comparing the level of CTGF protein (mRNA) in the sample to a standard level of CTGF protein (mRNA), wherein an increased level of CTGF protein (mRNA) is indicative of the presence of the renal disorder (diabetic nephropathy) of claim 1; wherein the increased levels of glucose are associated with diabetes (diabetic nephropathy) of claim 2; A method for diagnosing a renal disorder in a subject having hyperglycemia (kidney fibrosis), the method comprising: (a) obtaining a sample from the subject; detecting the level of CTGF protein (mRNA) in the sample; and (c) comparing

the level of CTGF protein (mRNA) in the sample to a standard level of CTGF protein (mRNA), wherein an increased level of CTGF protein (mRNA) is indicative of the presence of the renal disorder (diabetic nephropathy) of claim 7; wherein the hyperglycemia is associated with diabetes (diabetic nephropathy) of claim 8; A method for diagnosing a renal disorder in a subject having diabetes (diabetic nephropathy), the method comprising: obtaining a sample from the subject; detecting the level of CTGF protein (mRNA) in the sample; and comparing the level of CTGF protein (mRNA) in the sample to a standard level of CTGF protein (mRNA), wherein an increased level of CTGF protein (mRNA) is indicative of the presence of the renal disorder of claim 32.

Claims 1-2, 7-8, 32 and 35 are included in this rejection because CTGF mRNA expression is an indirect measure of CTGF protein.

The claimed invention differs from the prior art by the recitation of measuring CTGF protein using **an antibody specific to CTGF** in a **urine** sample.

Gygi et al. teaches that the correlation between mRNA and protein levels is insufficient to predict protein expression levels from quantitative mRNA data.

The '517 patent teaches using a urine sample to detecting the level of albumin in a urine sample using an antibody specific for albumin to assess renal function and degree of kidney damage (In particular, column 1, lines 16-19, column 3, lines 6-11, column 9, lines 47-55 and claims 1 and 9).

One of ordinary skill in the art would have been motivated to measure protein as taught by Gygi et al. in the CTGF detection method of Ito et al. because Gygi teaches that mRNA

expression levels are not a good indication of CTGF protein expression levels. Therefore, it would be obvious to measure the CTGF protein levels in the renal fibrosis kidney specimens to confirm the mRNA results. It would have been obvious to use the urine sample of the '517' patent in the method of diagnosing a renal disorder associated with kidney fibrosis of Ito et al. because Ito et al. teaches detecting CTGF in a sample containing CTGF. The '517 patent teaches that urine is a sample containing a marker (albumin) that is associated with kidney damage and renal dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art to use a sample that comes directly from kidneys which has been known in the past to contain markers for kidney damage and renal dysfunction in the method for diagnosing a renal disorder by measuring the level of CTGF in that sample.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "Applicants submit that Ito et al. describes the expression of CTGF mRNA in human kidney biopsy specimens to assess the correlation between interstitial CTGF mRNA expression and chronic tubulointerstitial injury. Ito et al. does not teach or suggest a method for "diagnosing a renal disorder... [by] detecting the level of CTGF protein" as recited in instant claims 1, 2, 7, 8, 32, and 35. Additionally, Ito et al. does not teach or

suggest a method for diagnosing a renal disorder by detecting the level of CTGF protein in a "urine sample" as recited in the instant claims.

The deficiencies in the teachings of Ito et al. are not remedied by Gygi et al. The Examiner stated that one of ordinary skill in the art "would have been motivated to measure protein as taught by Gygi et al. in the CTGF detection methods of Ito et al. because Gygi et al. teaches that mRNA expression levels are not a good indication of CTGF protein expression levels." (Office Action, page 21.) Gygi et al. examined the relationship between yeast mRNA levels and yeast protein expression levels for selected genes expressed in *Saccharomyces cerevisiae.* Ito et al. examined CTGF mRNA expression in kidney biopsy samples. Applicants submit that neither Gygi et al. nor Ito et al. teach or suggest a method of diagnosing a renal disorder by detecting the level of "CTGF protein" in a "urine sample," as recited in the instant claims. As neither of these references, alone or in combination, teach or suggest the methods recited in claims 1, 2, 7, 8, 32, and 35 in the instant application, Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Ito et al. in view of Gygi et al. be withdrawn."

It is the Examiner's position that one of ordinary skill in the art would have been motivated to measure protein as taught by Gygi et al. in the CTGF detection method of Ito et al. because Gygi teaches that mRNA expression levels are not a good indication of CTGF protein expression levels. It would be obvious to measure the CTGF protein levels in the renal fibrosis kidney specimens to confirm the mRNA results. It would have been obvious to use the urine sample of the '517 patent in the method of diagnosing a renal disorder associated with kidney fibrosis of Ito et al. because Ito et al. teaches detecting CTGF in a sample containing CTGF. The '517 patent teaches that urine is a sample containing a marker (albumin) that is associated with kidney damage and renal dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art to use a sample that comes directly from kidneys which has been known in the past to contain markers for kidney damage and renal dysfunction in the method for diagnosing a renal disorder by measuring the level of CTGF in that sample.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 28, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER